REMARKS

Applicant has amended claim 1 and has cancelled claims 12-20. Care had been taken to avoid the introduction of new matter. Claims 1-11 and 21-24 are presently pending in the application.

The Office Action provisionally rejected claims 1-8 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5 and 8-10 of copending U.S. Application No. 10/375,451. In response to this obviousness-type double patenting rejection, Applicant submits herewith documentation establishing common ownership between the present application and U.S. Application No. 10/375,451 and further submits herewith an executed Terminal Disclaimer.

The Office Action rejected claim 11 under 35 U.S.C. 112, first paragraph, as allegedly failing to comply with the written description requirement. Regarding this rejection, Applicant respectfully disagrees, and directs the Examiner's attention to the paragraph bridging pages 9 and 10 of Applicant's Detailed Description section of the presently pending patent application. That language states that healing membranes of the present invention can be impregnated with a therapeutically effective amount of an anti-scar forming agent. The cited language further mentions that angiotensin antagonists have been found to reduce tissue scar formation, referring to, for example, U.S. Patent No. 6,211,217 and incorporating by reference that disclosure into the present application. It is respectfully submitted that, according to a preferred embodiment of the present invention, the healing membranes are impregnated with an angiotensin antagonist. Without wishing to limit the invention to any theory or operation, Applicant believes that the present healing membrane can be constructed and used to resorb and advantageously release the anti-scar forming agent into surrounding tissues. Applicants accordingly request that the rejection based on Cohn et al. be reconsidered and withdrawn.

The Office Action also rejected claims 1-11 and 21-24 on prior-art. Regarding this prior-art rejection, claims 1-11 and 21-24 were rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Cohn et et al. (U.S. Patent No. 6,136,333). Applicants respectfully disagree with this rejection.

Independent claim 1 has been amended as set forth above. Applicant respectfully traverses this rejection, as it relates, in particular, to the claims even before the present amendment but especially after the entering of this amendment. Applicant submits that the present claims are not obvious over Cohn et al. In particular, Applicant submits that the reference, alone or in combination with any other prior-art reference of record, does not provide the required suggestion or motivation to render any of the present claims obvious under 35 U.S.C. § 103(a).

Regarding the outstanding rejection, it is well established that a claim can be rejected on obviousness grounds only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior-art reference or combination of prior-art references. Thus, for a rejection under 35 U.S.C. 103(a) to be proper, every limitation recited in a claim, which is rejected as being obvious in view of one or more prior-art references, must be disclosed or taught in that prior-art reference or referencess. In the instant case, Applicant respectfully submits that the cited reference neither discloses nor suggests each and every element that is recited in the rejected claims. Accordingly, as set forth herein, the outstanding rejection under 35 U.S.C. § 103(a) is improper and should be withdrawn.

Applying the above standard, the Cohn et al. reference does not disclose or suggest a method for promoting healing of damaged tissue after an open heart surgery, the method including, among other things, providing a substantially planar healing membrane which is (a) substantially-smooth on at least one side; (b) substantially uniform in composition; (c) about 10 microns to about 300 microns in thickness; (d) non-porous; (e) constructed from a resorbable

polymer base material consisting essentially of a material selected from the group consisting of a poly-lactide polymer and a copolymer of two or more lactides; and (f) adapted to be resorbed into the mammalian body within a period of approximately 18 to 24 months from an initial implantation of the healing membrane into the mammalian body; and placing the healing membrane adjacent to an opening in pericardial tissue of a patient so that the pericardial tissue surrounding the opening can regenerate over the healing membrane, as recited in independent, amended claim 1.

Applicant respectfully submits that all of the limitations of the presently pending claims may not have been properly considered by the outstanding Office Action. For example, the wording of the Office Action in the subject rejection may have overlooked discussing in detail and elucidating one or more of the following: thickness limitations in one or more of claims 1, 4 and 5; the "non-porous" (defined in the specification) limitation in claim 1; placement of the healing membrane adjacent to an opening in pericardial tissue as described in claim 1; regeneration of pericardial tissue over a healing membrane spanning an opening in pericardial tissue following open heart surgery as set forth in claim 1; attachment of the healing membrane to pericardial tissue as recited in claim 9; the recited heat-bonding attachment of the healing membrane to pericardial tissue of claim 10; the limitation of claim 11 requiring the healing membrane to comprise angiotensin antagonists; the limitation of the healing membrane being precontoured into a heart-shaped bag to surround the apex of a heart as recited in claim 22; the limitation of the healing membrane being precontoured into a tube to facilitate placing of the healing membrane around the conduit of a left-ventricular assist device (LVAD) as recited in claim 23; and the limitation of the healing membrane being precontoured to facilitate placement of the healing membrane over a pump of a left-ventricular assist device (LVAD) as set forth claim 24.

With reference to the Manuel of Patent Examining Procedure (MPEP), Section 706.02(j), entitled "Contents of a 35 U.S.C. 103 Rejection," states that rejections under 35 U.S.C. § 103

must address each limitation of the claim. Here, limitations, such as, to name a few, thickness, composition, use, and shape recitations, of the claims may not have been adequately addressed by the Office Action. For example, regarding rejections under 35 U.S.C. § 103 where, to meet the claim, it is necessary to modify a single reference or to combine it with one or more other references, Section 706.02(j) states that the examiner should set forth in the Office action "the difference or differences in the claim over the applied reference(s)." Moreover, according to Section 706.02(j), "[t]o establish a prima facie case of obviousness . . . the prior art reference (or references, when combined) must teach or suggest all the claim limitations," Applying this guideline to the present Office Action, it would appear that all of the limitations of, for example, one or more of claims 1, 4, 5, 9-11 and 22-24, to name several, may not have been shown, or even alleged as being shown, to be disclosed or suggested in the prior art references of record. Accordingly, each of the limitations of the rejected claims has not been addressed by the outstanding Office Action.

While the Office Action did appear to endeavor to address and analyze the thickness limitation of, for example, Applicant's claim 1, this analysis was not sufficient to establish a *prime face* case of obviousness. In particular, as an example, the Office Stated that Cohn et al. discloses a thickness of 0.25 microns (i.e., 10 mil), but Applicant's claims 1, 4 and 5 recite thicknesses of 10-300 microns, 100 microns, and 200 microns, respectively.

Applicant's claims thus would appear to define embodiments having thicknesses that are from 50-1500 times greater than the thickness referenced in the Cohn et al. reference.

Regarding the unique constructions and compositions of Applicant's claimed combinations, such as the exemplary "thickness" one just discussed, at the time of the present invention it was surmised or contemplated by the Applicant that the present healing membranes, when formed to thicknesses of about 10-300 microns, would be capable in certain implementations of causing relatively rapid rates of absorption, as compared to thicker healing

membranes of the same construction. Such relatively rapid rates of absorption could potentially cause one or more of (a) undesirable drops in pH levels causing (b) local inflammation, (c) discomfort and/or (d) foreign antibody responses, and, also, could potentially cause (e) unwanted tissue turbulence from the roughened, biodegrading surfaces. The resorbable polymer healing membranes, in accordance with this aspect of the present invention, were thus designed to comprise a composition and commensurate thickness that would facilitate biodegradation in the body at a relatively slow rate. (See page 10 of Applicant's specification.)

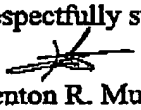
The Cohn et al. membrane, on the other hand, comprises a quite different composition, which certainly does not appear to resemble that of Applicants' claimed healing membranes constructed "from a resorbable polymer base material consisting essentially of a material selected from the group consisting of a poly-lactide polymer and copolymer of two or more lactides." (See claim 1.)

Moreover, in contrast to the present invention, as Cohn et al. apparently does not form its membrane of the same material as Applicant, the Cohn et al. reference would appear not to have or may not have been presented with one or more of the afore-mentioned problems encountered and addressed by Applicant's claimed constructions. Consequently, it would appear that the Cohn et al. membranes, being formed of quite different materials, were also, and/or consequently, formed to have different thicknesses.

In view of the foregoing amendments and remarks, it is respectfully submitted that independent, amended claim 1, and the claims dependent thereon, are neither anticipated nor rendered obvious by Cohn et al., taken separately or together with any other reference of record. Applicant accordingly requests that the rejection based on Cohn et al. be reconsidered and withdrawn.

Allowance of all presently pending claims is respectfully requested. If a telephone conversation with Applicants' attorney would expedite the prosecution of the above-identified application, the Examiner is urged to call Applicants' attorney at the below number.

Respectfully submitted,



Kenton R. Mullins
Attorney for Applicants
Registration No. 36,331

STOUT, UXA, BUYAN & MULLINS, LLP
4 Venture, Suite 300
Irvine, CA 92618
Tel: 949-450-1750
Fax: 949-450-1764